REQUIREMENTS FOR USE OF IRB AUTHORIZATION AGREEMENT UTILIZING THE CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC) IRB

For any institution to list the CDC IRB as an IRB of record on their FWA, an IRB Authorization Agreement (IRB AA) form must also be completed and approved by CDC. An IRB AA form is only authorized to be submitted to CDC when CDC is engaged in the research and the CDC IRB has already reviewed or will be reviewing the protocol. CDC requires a separate IRB AA form to be completed for each protocol. For use with more then one protocol requires a prior approval between CDC and the other institution.
The IRB AA form must be signed by the signatory official who signed an institution's FWA. Please fill in all of the information regarding your institution and the signatory official and have the form signed and dated by the signatory official before sending the IRB AA to CDC.
Please mail the completed/signed IRB AA form to the following address:

CDC
ATTN: Virginia Talley (E-81)
1600 Clifton Road, NE
Atlanta, GA 30333
Phone: 404 498-3110
Fax: 404 498-3115

Once the original signed IRB AA form is received by Virginia Talley, she will have the CDC signatory official sign the form and will mail or fax copies to the individual you have designated to receive the official copy for your files. She will also mail copies to the CDC investigator for filing with the protocol. The CDC investigator is also required to fax or mail copies of the IRB AA form to the local investigator to keep on file and provide copy to the local IRB or at least verify if a copy was received directly from CDC.
OHRP requires the completed IRB AA form to be kept on file by CDC and the local institution/IRB offices and available for inspection upon request by OHRP.

IRB Authorization Agreement
With
CDC as IRB Responsible for Review of Protocol(s)

Name of Institution or Organization Providing IRB Review (Institution A):
Centers for Disease Control and Prevention (CDC)
IRB Registration #: **IRB00000** Federalwide Assurance (FWA) #: **FWA000001413**

Name of Institution Relying on the Designated IRB (Institution B):

OHRP Federalwide Assurance (FWA) #: **FWA0000**

The Officials signing below agree that (Institution B) may rely on the designated IRB for review and continuing oversight of its human subject research described below: (*check one*)
(___) This agreement applies to all human subject research covered by Institution B's FWA.

(_X_) This agreement is limited to the following specific protocol(s):
Name of Research Project:
IRB Protocol Numbers for both institutions: CDC #_____ / _____ #_____
Name of Principal Investigator:
Sponsor or Funding Agency: _____ Award Number, if any: _____

(___) Other (*describe*):

The review and continuing oversight performed by the designated IRB will meet the human subjects protection requirements of the HHS regulations for the protection of human subjects at 45 CFR 46 as well as the requirements of Institution A's OHRP-approved FWA. The IRB at Institution A will follow written procedures for reporting its findings and actions to appropriate officials at Institution B. Relevant minutes of IRB meetings will be made available to Institution B upon request. Institution B remains responsible for ensuring compliance with the IRB's determinations and with the terms of its OHRP-approved Assurance. This document must be kept on file at both institutions and provided to OHRP upon request

Signatures:

Authorized Official of (A): CDC	**Authorized Official of (B): MNDH**
_____ _____	_____ _____
(signature) (date)	(signature) (date)
Virginia L. Talley, B.S.	Name & degrees of Signatory Official
Assurance Coordinator	Position Title
Centers for Disease Control and Prevention (CDC)	Name of Institution
1600 Clifton Road, NE (MS E-81)	Address
Atlanta, GA 30333	
(phone) 404 498-3110 (fax) 404 498-3115	(phone) (fax)
(email) vlt0@cdc.gov	(email))